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## PRESENTATION

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### **Alexander Rosar - Bayer AG - Head -- IR**

So ladies and gentlemen, good morning. And welcome also on behalf of the entire Bayer management team to our first Meet Management conference here in London. We are really happy that so many of you followed our invitation.

Meet Management is a conference format we invented some six, seven years ago with the aim to give you broad access to our senior executives. Consequently, the focus is on discussions and the exchange of opinions.

So what have we prepared for you? Firstly, a presentation by our CEO, Marijn Dekkers, focusing on the strategic priorities of the Group. Secondly, an update on our pharma R&D pipeline by Andreas Busch. He is heading the Research at Healthcare, and Kemal Malik, he is heading our Development department. Thirdly, probably the most interesting part of the agenda, four hours breakout for our discussions and, as I mentioned, exchange of ideas.

My name is Alexander Rosar and I'm responsible for Bayer's Investor Relations program.

With that, I'd like to hand over to Marijn for his opening presentation. And I will be back after his presentation for some organizational remarks. Thank you. Marijn.

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### **Marijn Dekkers - Bayer AG - CEO**

So good morning, ladies and gentlemen. I hope you can hear me okay in the back. Just want to add to what Alexander says. Thank you very much for coming to our management meeting today. We hope to have some stimulating discussions with you. It's normally not a problem with you, so we're counting on it again today.

And what I would like to do is just in 15 or 20 minutes, run through some of the key points that we are trying to bring across today where I would say that, probably, one of the most newsworthy items that we're talking today is our plans with our development pipeline and the new products we've introduced from the Life Cycle Management. And for that, our two experts, Andreas Busch and Kemal Malik will come immediately after me to give you a deeper insight in that.

So I will start with the disclaimer. You're all familiar with that. (See "Disclaimer" chart at the end of this transcript).

And just quickly review the business highlights for the first half financially.

We are on track for the year, we believe, with very strong growth momentum in our two life sciences businesses -- Healthcare and Crop Science. And also very encouraging is that we were able after the first half of the year to increase the targets for the new products, the new pharma products, from EUR1 billion to EUR1.4 billion in sales for this year.

Material Science -- a relatively weak performance so far this year in a challenging environment for the chemical industry. In spite of that, we have maintained our 2013 outlook, believing that the good momentum in the two Life Sciences businesses will compensate for some of the weakness that we see in Material Science.

Just a quick snapshot so far -- 4% organic sales growth, 29% EBIT, 1% EBITDA. And then core EPS so far in the first half of this year by 4%.

Our guidance, as I said, we reiterated after the first quarter we said it looked increasingly ambitious, 4% to 5% sales growth, mid-single digit in adjusted EBITDA growth and then core EPS in the high single digits percent increase.



Now the strategic priorities that I will just quickly touch on are, of course, in pharma the successful commercialization of those five new products, the investment in Life Cycle management of those products. And then also an update on our early to mid-state pipeline, our ambitions for the pipeline. And you will hear about that shortly.

In Consumer Health we have an aspiration to become the number one over-the-counter company in the world. We are currently number two. I'll talk a little bit about that.

CropScience -- we want to grow above the market, but a benchmark profitability. And benchmark profitability means that a profitability level in EBITDA margin that is one of the highest in the industry. And there, also important, is that we expand our capacity in some of our key crop protection products. And then Material Science, the theme is to improve our returns.

So let me start with Pharma. Some time ago, we communicated the ambition to have a CAGR of top line growth in Pharma of 7% between 2012 and 2015. And that's really driven by those five new products that I was talking about before.

Xarelto -- I'll start with Xarelto. And, again, this, I'm sure, will be the subject of quite some discussion in the breakouts as well.

So far, really so good with Xarelto. You can see here there's a share of the new anti-coagulants globally where Xarelto has now close to 20% share of the total market, including Warfarin. Then the bigger trend is around 15%. And you can see apixaban is around 1%. So we're very pleased with the momentum we have, but particularly after the approval for SPAF early last year.

And the beauty there of Xarelto is, of course, we are once daily, which the competitors are not. And we have a relatively wide range of indications. And that is helping us drive this growth.

The other four -- Eylea, Stivarga, Xofigo and Adempas are all being launched. Eylea in this year for the first year outside of the US. Last year, Regeneron, our partner, introduced the product in the US. So we've had very good, positive introductions in Japan and Australia where we have about already 50% market share after less than a year on the market. So the pickup there is very good.

Stivarga, up to this point, 15,000 patients treated. Good momentum there. And a new approval in Europe for mCRC recently in August.

So Xofigo for bone metastasis, for prostate cancer -- good first initial pickup. Also indicated by the fact that we now have 473 patient-ready centers. This is a radioactive medication, so not everybody can just use this product without certain approvals. And the fact that we're almost with 500 clinics who can now use this product with patients is a very positive sign.

And then last, but not least, Adempas. I don't know if it's easier to pronounce than riociquat. I guess it is. But it's now a commercial name -- Adempas. And there the highlight is that last month we got the first approval for commercial introduction in Canada. So that's also now a commercially introduced product for pulmonary hypertension in particular.

And that makes these five sort of 2011, '12 and '13, as you see on this chart, it's been very, very busy introducing these new products. We spent a lot of money introducing these products, needless to say. But this is money well-spent, we think. And you can see here that the overall peak potential of EUR5.5 billion is expected in sales for these five products. And you can see the breakdown for each of the products along the timeline.

Now these products have more potential in additional indications than what they have been approved for so far. And this is a quick overview of the five products and their potential and our lifecycle management plans for these products. But since the speakers after me will go into more detail on this, I won't spend any more time on it. But be assured that we are maximizing the opportunity of these five products also in other indications for which they are not approved today. And of course, this is also a significant investment on our part in the further development of these five assets.

Then, this is somewhat new. We are going to spend some significant time with you today to talk about what's next. And I, of course, meet a lot with all of you, with our investors and there is always this question, "What have you done for me lately?" I don't know if you can relate to that question, but that's why we're here. And we really wanted to spend the time today to carefully explain to you how we think about 'what are we doing for you lately.

So that's what this page represents. Basically, five pipeline compounds -- new active ingredients, all five of them, that we are hoping to bring all into Phase III status by 2015. And you can see here, one is an oncology, two heart failure, one renal anemia, and one women's health compound. And again, more details on this in a minute.



Number one leading OTC company. This is a very different business in healthcare but a very exciting business where we have been able, over the last few years, to gain significant market share. And we're very ambitious to use the overall Bayer brand, the recognition of that brand.

And the opportunity we have to position certain products that are very successful in certain countries but not present in other countries, particularly not in emerging countries. And try to, basically, cross-fertilize the world with some of our most successful product brands. And that's the strategy that we have. And we get really good growth out of that in the last few years.

In addition, of course, we want to do particular bolt-on acquisitions to strengthen the portfolio or strengthen certain presence in certain regions. So we're very optimistic for this. And there's a lot of organic growth that can be had by us using these product brands more broadly and more strongly across the globe.

Talking about bolt-on acquisitions -- just a quick reminder of two that we did very recently -- Conceptus and Steigerwald because they represent sort of the thought process behind these bolt-on acquisitions.

Conceptus is the permanent birth control methodology. It's the only way for a woman to have permanent birth control protection without undergoing surgery. And this is a very good addition overall to our women's health portfolio. And there's more detail on that in the handout and an opportunity to talk more about that in the breakout.

And then Steigerwald is one of those examples of an additional capability in our over-the-counter consumer care portfolio. This is a product line that is essentially only sold in Germany where we have in our global setup an opportunity to take it to other countries as well. And that's where the synergies will be coming from. So that's Healthcare.

Move on to Crop Science. Crop Science, again, the target for top line growth between 2012 and 2015 CAGR of 6%. We're targeting, as I said, the above market growth but a very good, high benchmark profitability. And I would say there's a lot of similarity between Crop Science and Pharma in the sense that also there our innovation focus is paying off with the introduction of new products. We just depict it differently.

In the Crop Science industry, often a metric that is being used over a ten-year period of time. In this case, for us, starting in 2006, what sales do you derive from products that are introduced in that decade. And you see that in 2012 we had a 60% improvement to EUR1.1 billion from EUR0.7 of new products. And that momentum will continue over the next few years. And these are products in different areas, particularly fungicides or herbicides or insecticides. But not just that. Also on the seed side of the house we have a lot of innovation that is being introduced.

Now you have seen that the Crop Science industry has had the last two or three years really quite a good performance. And so have we. And this leads to a requirement on our part to increase our capacity on certain active ingredients.

And you can see here the capital expenditures that we plan to invest in Crop Science over the next number of years. Coming from EUR300 million, we're basically doubling that over the next few years to build these additional capacities for different products.

And the one very exciting one is there, number two, glufosinate-ammonium, which is our Liberty product. And that is an herbicide that a broad spectrum herbicide that is in more and more demand because weeds, particularly in North America, have grown resistance to Roundup, to Glyphosate. And this is a very, very effective alternative for those farmers who are struggling with the resistance that weeds have developed. This is what makes the demand for this product significantly increased. And, again, I'm sure this will be a topic for the breakout.

We've also done bolt-on acquisitions in Crop Science in two areas. As I mentioned, seeds is an area where we would like to get stronger. We've done some vegetable seeds. We've done soya, in particular -- oil seed type of acquisitions to get access to germplasm, in particular.

And then one other area we're very interested in is biological crop protection. So this is in contrast to chemical crop protection. Biological crop protection are basically biological agents, biologically derived agents, that protect crops from, say, fungi or insects.

Material Science is a business that at the moment, just like I would say a lot of peers in the chemical industry, is somewhat struggling. The market, particularly in China, has become weaker for chemical products over the last nine to 12 months. In addition, Europe is rather soft. And capacity in the industry is relatively high and not really completely used.

So one of the ways to sort of demonstrate what's been happening is capacity utilization is not at its maximum. And that makes it, for us in Material Science, at the moment hard to pass on increased raw material costs. And we have suffered from increased raw material costs as a result of the political instability over the last few years, particularly in oil producing regions in the world.



So this is a chart that sort of illustrates, over the last two, three years what has happened. I think it's a good illustration. You see from 2010 to 2012 in green. Our revenue increased from EUR10.2 billion to EUR11.5 billion. That sort of sounds good, right? EUR1.3 billion more sales in two years.

However, if you look at the gray bar next to it, that is our raw material and energy costs, which increased in that same period of time by EUR1.2 billion. So proportionately, a stronger increase in our input costs than in our revenue. And that, then, means that our adjusted EBITDA is sort of staying at a EUR1.4 billion, EUR1.2 billion, EUR1.3 billion level.

We cannot leverage that extra sales for extra profit because our input costs have gone up, actually, proportionately more than our sales. And that's the result of the fact that there's over-capacity because if there wouldn't be over-capacity, it would be easier to pass on these higher costs to our customers.

Now I'm actually optimistic that this scenario will change in the next few years. I'm not optimistic that the geographic uncertainty will diminish. I think that will still be there in a few years. But I think the capacity utilization in our industry will get better, will improve just with global growth. And it will make it easier for us to pass on these increased costs to our customers. And that will help us, I think, going forward in the next few years to improve the returns and improve the margins again in Material Science.

So with that, let me just quickly summarize first half business performance, mainly driven by Life Sciences within Pharma, very good product launches.

You've heard -- and this is sort of a theme -- and you will hear with the next speakers as well, there's an additional investment in R&D, particularly in Pharma required to make sure we optimally use those five new products -- also for new indications. And we nurture along the five pipeline compounds.

And then production capabilities -- this is specifically the Crop Sciences target for active ingredients where we have high demand -- make sure we have the capacity available.

So with that, I would like to wrap it up. Thank you. And then we'll go to Professor Andreas Busch who leads our Healthcare and Pharma research efforts. And then Andreas will be followed by Kemal Malik who leads our Development effort. Thanks.

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**Andreas Busch - Bayer AG - Head -- Global Drug Discovery**

Thank you, Marijn. And thank you for having the chance to describe to you our research strategy. And I hope that I can, within the next 20 minutes or so, convince you that we have the appropriate strategy, the right focus and the commitment to deliver in order to deliver to you what you want to see next.

So what I'm going to talk about, I'm going to talk about, like Marijn indicated, a first selection of compounds which we have picked for, in our opinion, very obvious and very clear reasons to accelerate and move into Phase III within the next two years. Kemal after me will then talk about how we want to maximize the value through Life Cycle Management activities of the compounds which we have just recently launched.

We do think that we have a very focused and clear R&D strategy in place in which we identified the areas where we believe there is a particular high unmet medical need, combined with the fact that we have a specific expertise -- long time expertise in this area where we can be competitive. And we think that we can leverage mechanisms on those focus areas beyond the focus areas.

Let me just quickly say that we think that looking at cardiology and hematology, we have built up a track record and we have a clear idea where there are still indications with very high unmet medical need in which we can produce very valuable assets. And I think I can show you in the pipeline what we have produced so far.

In oncology, we have the aspiration to be best-in-class on a number of signaling cascades listed here, cell cycle, immunotherapy where we are engaged in human metabolism in particular.

And we're going to, of course, continue our efforts in gynecological therapies where we believe we are a very particular competitive players, but where also we believe there is a huge unmet medical need, particularly in the areas of uterine fibroids and endometriosis where a high percentage of the pre-menopausal women are affected by and have a dramatic impact on their quality of life.

So clearly, we believe our R&D strategy focuses on innovation in areas with high unmet medical needs. And we are ready to deliver on those.

If we look at our pipeline -- and I'm going to talk only about the early clinical development pipeline -- you can see that we have clearly enriched this pipeline over the past few years. We have right now over 20 compounds in Phase I and Phase II. We have backed those early clinical development compounds with another 20



preclinical development compounds. So we do think that we are ready to deliver continuously assets with very good productivity, with a very clear focus and with a very good quality for the compounds.

We have chosen, for a number of reasons, five of those compounds in early clinical development phase to accelerate, to focus on. And I hope you can really follow me in seeing that our focus is on delivering fast to the patients with higher unmet medical needs.

Those five compounds I've circled, those five compounds we have particular experience in the molecular structure. We have a particular experience in the mechanism they act on and within the disease. Therefore, we do think that with these five compounds we have a significantly higher probability of taking the success than for a number of other compounds right now in clinical development.

What are those compounds? First of all we talk about a PI3-Kinase Inhibitor. There are a number of PI3-Kinase Inhibitors around in development pipelines. We do think that we have a very unique protein -- PI3-Kinase Inhibitor with Copanlisib. And I'll let you know on the next few slides what is so specific about it.

We also have a compound move forward, Finerenone, which is a mineralocorticoid receptor antagonist, a non-steroidal. And I will tell you what the particular advantage, competitive advantage, of this MRA for us represents.

We have moved forward Molidustat, which is a hypoxia-induced factor prolyl hydroxylase inhibitor, a compound which can be used in anemia to increase EPO. And the consequence, of course, act against anemia.

We also have moved forward an sGC-Stimulator, a stimulator of the soluble guanylate cyclase, an area where we have a particular expertise in. That's a very central second messenger in the cell, which acts not only on vasoregulation but also on fibrosis and proliferation. And therefore, we do see a huge number of potential applications of this compound.

Right now, with the first focus, we are going for worsening chronic heart failure. And finally, within our gynecological therapies, we focused on a field of long built-up experience on progesterone antagonism. And we have identified a compound with particular positive features when it comes to efficacy and the MPK profile. And we are going to study this in symptomatic uterine fibroids.

Let's go first to Copanlisib, our PI3-Kinase Inhibitor. As probably most of you know, PI3-Kinase Inhibitor is a very crucial role in the proliferation and therefore, in the progression of a number of tumors.

The number of important factors stimulate PI3-Kinase. But what is very important to understand is that PI3-Kinase comes not only as the PI3-Kinase but in very different, very distinct subtypes, which react to different growth factors.

We have identified in our preclinical experiment that, in particular, the Alpha and the Delta subunits are crucial for the generation and progression of cancer. And we have therefore searched and optimized a couple of compounds as particular PI3-Kinase Alpha Delta inhibitors compound. It is exactly this type of inhibitors and with this compound we have shown in preclinical models in broad anti-tumor spectrum.

We are now in Phase II in non-Hodgkin's lymphoma. We complete this by the end of 2014. And we are ready to go into Phase III by 2015.

I'll just show you very impressive response in follicular lymphoma patients with a clear partial response. And as you can see, already at the third cycle, you see the lesions dramatically reduced. And we see a spectacular 100% of the patients responding to the treatment in that particular trial. Each patient has really responded partially to it.

We have from this study still patients on trial. Maximum response duration right now with the first patient involved is over 140 days. And we have first encouraging results also in other lymphomas such as in diffuse B cell lymphoma patients. So, therefore, we feel that this particular compound is a very valuable asset in our oncology portfolio. And is a very competitive compound taking it forward.

Let's switch to gynecological therapies where we have buildup, obviously, over the decade, significant experience, particularly in the area of steroidal progesterone and estrogen receptors. And probably a lot of you know that progesterone and stimulation of the progesterone receptor generate transcription of a number of important proteins in the uterus means that it increases endometriosis modulation and potentially also fibroid growth. And our approach, of course, was then to try to lock very early on the progesterone receptor, thereby inhibiting both aspects of endometriosis as well as fibroid growth.



Fibroids are very important with a huge unmet medical need. Five percent to 10% of the pre-menopausal population suffers from symptomatic fibroids. And symptomatic fibroids are really an ugly thing. You have a significant impact on your quality of life. You have very heavy bleeding. You have, of course, symptoms related to the size of those fibroids, which can be multiple size of a tennis ball. And you can imagine what they do in your stomach if you have them growing there.

Current therapies are clearly insufficient. They include GnRH treatment, which of course has the typical estrogen-depleting side effects. And of course, you can go about uterine fibroids with surgery, which is obviously also not completely uncomplicated.

The course of fibroids strongly depends strongly on both estrogen as well as progesterone. Therefore, like I said, progesterone receptor modulation for us seems to be a very clear path forwards.

And we have optimized the compound. Our sPRM BAY 1002670 for the treatment of symptomatic uterine fibroids.

What we did with this compound in a first study in patients was we looked at what dose can we generate at all. More than 60% of amenorrhea really stopped bleeding. And what you can nicely see here in this dose response curve is that at doses higher than 0.5 milligrams, starting at 1.0 milligram, you clearly surpass the 60% of population line. And you get an almost complete amenorrhea at every dose higher than 1.0 milligram. So therefore, we can show a very nice, very strong proof of concept with this compound.

The compound reduced bleeding. This reduction of amenorrhea was nicely reversible upon removal of the compound. And we did not see any significant safety findings. And therefore we feel very comfortable moving this compound as quick as possible forward.

Anemia is another very important area which we researched on in our cardiovascular background, in our cardiovascular research as a part of our renal disease aspect.

Diseased kidneys cannot produce what's very important for your blood, which is EPO. The normal kidney functions in a way that it reacts to hypoxia by producing EPO. The diseased kidney cannot do that. And we understand, meanwhile, the mechanism that are involved in producing EPO, as well as what we can potentially do to interfere with the lack of EPO production in diseased kidneys.

What you should keep in mind is, of course, that kidney diseases are already important as they are right now. But the incidents of diseased kidneys will increase dramatically in the future as the consequence of increased obesity.

As a consequence, then, of increased diabetes, and as a consequence of type II diabetes, you will dramatically increase, of course, the number of diabetic neuropathies. And as a consequence, end stage renal disease.

We have identified, like I said, HIF-PH as a very critical mechanism for the stabilization and production of EPO. Like I said, in low oxygen level what you have is the hypoxia-induced factor, which in the nucleus increases transcription and production of EPO. At normal oxygen levels, indeed, the protein here, the HIF-PH, oxidizes. It, therefore, destabilizes HIF and as a consequence you cannot produce EPO anymore.

Our approach is to inhibit HIF-PH. And as a consequence, increase EPO. And that's exactly what we've done. As you can see in the study now through volunteers, Molidustat, which is a very specific, highly potent compound for HIF-PH with a very nice pharmacokinetic profile.

We have put it into the development for the treatment of anemia associated with chronic kidney disease. And what we saw is that we see a significant increase of EPO levels already at 12.5 milligram. And within a week, as a consequence of the increased EPO levels, already a significant increase of reticulocytes starting at doses of about 30-37 milligrams. So, clearly, a very positive, very effective compound, which we want to continue in the development for renal anemia.

Another mechanism we have really significant experience on, and quite a success for the good of patients, is our soluble guanylate cyclase, which we have a further optimized compound with high affinity to the soluble guanylate cyclase as well as a very positive pharmacokinetic profile which makes this compound a potential once daily compound. What we want to do is we want to take this compound based on its efficacy forward in patients with worsening heart failure.

What you should know is heart failure is, of course, a very, very bad disease with huge death rates -- death rates higher than most of the cancers we know. However, there is a distinction. And you cannot very easily, based on NYHA classification, predict how long a patient is going to live because we do have very often stable patients also at NYHA 3, or even at NYHA 4. However, what you also have is once you hospitalize those patients first, once they had really a crisis and they went into hospital, starting from that moment on, they worsened very dramatically, very quick.



So hospitalization is a clear predictor of worsening heart failure. And that, meanwhile, a very well-identified disease. That is the disease we're going for. There's a clear limitation of the available treatments in the disease worsening heart failure. And we do think that with sGC stimulation we can improve hemodynamics via restoration of the cardiac and vascular cGMP signaling, both in the cardiac myocyte as well as in the blood vessels. We do see a very positive aspect of cyclic GMP increase.

What you can see here is one result out of the study we've undertaken with this compound. And what you can see is that we are, indeed, are capable with this compound at therapeutic relevant doses of 7.5 -- 10 milligrams to dramatically increase the cardiac output. We can increase the output almost up to a liter per minute.

And what we can see with this compound is that it has really a significant positive effect on a number of important biomarkers and parameters. We can see not just the cardiac output but also the cardiac index, which is improved. We can see that the systemic vascular resistance goes down and that the stroke volume goes up.

And all this happens in the absence of significant effect on the blood pressure or with significant effects chronically on the heart rate. Therefore, we feel very, very positive about the potential of this compound in the modality of heart failure.

The final compound I'm going to present to you is our mineralocorticoid receptor inhibitor, MRA, which is a proven principle in the treatment of heart disease. You probably all know spironolactone and you all know eplerenone, which have proven to be effective in heart failure. However, their usability is very significantly limited. It's very significantly limited by their side effects because an increase in potassium in the blood to very dangerous levels, above five millimolar very quickly.

And, of course, based on their steroidal structure, they cause all sorts of steroidal-induced side effects such as gynecomastia, which is not in the first place an aesthetic problem for men, but very, very painful. And again has a huge impact on the quality of life.

We do believe that with our first non-steroidal, highly specific MRA we have a particular approach to address this receptor both in heart as well as in kidney. Because, again, it's important this receptor is expressed very highly both in the heart as well as in the kidney. And whereas in the kidney, it clearly increases sodium retention, it is important that in the heart, it can increase inflammation and fibrosis. Something you definitely don't want to see in the heart.

Therefore we believe with this compound, for which we have a profile in preclinical studies superior to spironolactone and eplerenone. We have a clear differentiated compound moving forward in that indication.

What we can see in the first Phase II findings is really a validation of this principle. A -- we can see that the highest dose we would potentially use, 10 milligrams, only very slight increase of potassium compared to spironolactone, which is not the maximum dose of 25 milligram. We only see about half of the potassium increase with the consequence that based on these results, we believe that we can dose the compound much higher and generate a much higher efficacy in Phase III trials later on.

We can see that one of the side effects, a significant reduction in glomerular filtration rate is significantly reduced by our compound seen in the middle.

And, finally, we do see a very positive effect on proBNP, a very important biological marker for the modulation of heart failure. So overall, what we can say so far with this first non-steroidal MRA is that these results suggest improved safety with at least the same efficacy. We, of course, do bank on an improved superiority in efficacy later on.

That sums up the compounds, which you will hear news about over the next couple of years. We have, of course, other compounds moving forward through Phase II and Phase III, which I had not referred to today. But overall, we believe that we are in a situation to continuously deliver the clear focus, high quality compounds into development and transition them through the value chain into our late stage clinical development where I am sure everybody is convinced Kemal will make the best out of them. Thank you.

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**Kemal Malik - Bayer AG - Head -- Development, Chief Medical Officer**

Good morning, ladies and gentlemen. I'm Kemal Malik, head of Global Development at Bayer.

First of all, good to see so many friends in the audience. I like to have the opportunity of speaking to you.

What I want to do is talk a little bit about the Life-cycle Management that we're going to do with the very exciting recent launches. But let me just first start off by reflecting on the last four or five years. We've had an unprecedented period of success in Bayer. Over that period of time, we've won 23 Phase III studies with our new molecular entities. Each one of them has been positive. We've had 100% track record in terms of regulatory approvals. We haven't had a single failure at that stage. And that is really an unprecedented track record. It shows our ability to innovate. But it shows our ability to turn that innovation into meaningful medical solutions for patients. A point I will come back to at the end of my presentation.



I make no apologies for starting with Xarelto. It is our flagship compound. It's been ten years of my life. And I think it is probably the most exciting compound we obviously have in the portfolio -- the [30] in terms of the marketed portfolio. We ran 11 Phase III studies. Each one of those were positive in terms of the primary endpoint. We're now approved in seven indications.

Now there's two very important points. The first is we have the broadest range of indications of any novel oral anticoagulant. And secondly, we are once-daily in the key chronic indication of stroke prevention, atrial fibrillation. Those were active decisions we made during development. They didn't kind of happen by chance. We made those choices. And physician surveys have shown why do they use Xarelto compared to other agents. The predominant factors are [impressive] indication at launch and the once-daily dosing. So we have shown that we have developed what I believe is the best novel oral anticoagulant on the market with the most complete profile at the time.

So we're not going to stop there. We have a significant Life-cycle Management program ahead of us. We've studied 60,000 patients prior to launch in stroke prevention, atrial fibrillation. Currently, the drug is being used by over 5 million patients worldwide. And we've accumulated over 1.25 million years patient exposure. But we now want to go forward.

Life-cycle Management will focus on two distinct areas. The first is to look at other areas where thromboembolism is important. And that is shown on the bottom right hand corner if you can look at the chart.

And those are looking at a more chronic area from our acute coronary syndrome study ATLAS -- once again, the only novel oral anticoagulant to show benefit in ACS - to look at a more chronic patient population. This is the so-called May study or COMPASS study that's being run by [Celine Yusef] in Canada. And we're going to look at patients who are ambulant with coronary artery disease and arterial disease. And it's a 20,000 patient study. And we're going to look at reducing cardiac events.

We're also looking at chronic heart failure in patients with ischemia. This is a large study also.

But also we want to round up the profile in atrial fibrillation. I talked about us wanting to be the most complete novel oral anticoagulant. And in the atrial fibrillation area, we're going to look at patients undergoing PCI, patients who are undergoing cardioversion and ablation. As I said, another 30,000 patients worth of studies will be ensued. This is larger than the development programs of other newer anticoagulants getting to the market. And that shows our commitment to this space.

Let me talk about Stivarga. This is our tyrosine kinase inhibitor. It has three modes of action -- anti-proliferate, anti-stromal, and anti-antigenic -- on leading indications where colorectal cancer and GIST. But we're going to expand that. We're going to look at HCC, liver cancer. There are no approved therapies after Nexavar. So if you fail on Nexavar or you progress, there is nothing available for you.

And we're going to study Stivarga in this patient population. And in addition, we're going to look at an earlier stage colorectal cancer, the third most common cancer in the world. And we're going to look at patients who've had a primary resection of a liver metastases. And then give them Stivarga. We're also going to look at expanding into other tumor lines with signal generating studies in Phase I and II.

Let me talk a little bit about Xofigo. I really think this is an incredibly interesting drug. It's Radium-223, an alpha emitter, yet preferentially taken up by bone.

Let me pause for a moment and talk a little bit about prostate cancer. As you all know, it's a very exciting area. And we say it's like number 10 buses in the U.K. You wait forever and then five come at the same time. I guess it's like therapies in prostate cancer. For a generation there was nothing and now a lot of us have come at the same time.

Having said that, Xofigo is unique because it targets specifically bone metastases, an area of considerable concern for patients because of the pain that that causes. But also we showed an improvement in overall survival -- a 44% improvement in overall survival were shown in our Phase III study. But we want to now expand from there.

If you think about prostate cancer, it goes through three distinct stages. Initially, it could be curative with surgery or radiotherapy. You then go through a period where it's hormone sensitive. And then you go into a period where it's so-called castrate resistant. Sort of advanced disease. And we're currently approved in that area, shown on the left where you've got symptomatic both in metastases and you've got metastatic disease.

We want to move to an earlier stage of that cancer therapy when the lesions are asymptomatic and in combination. And we're going to be running a Phase III study with abiraterone to look at this patient population.



Why is this important? Firstly, obviously, it'll increase the population that's available to be treated. But, secondly, the period of time they'll stay on the drug will obviously be longer because it's an earlier stage of the disease. So we're expanding the potential of Xofigo by doing this.

But there's some other stuff we're doing. One of the things we're going to be doing is looking at repeat dosing. In the Phase III program, we studied six cycles of therapy every four weeks. But we're going to look at patients who progressed with a new lesion after that at some point in the future. Maybe a year or two later, and give them repeat dosing.

We're also going to study higher doses. Our current program on our label is 50 KBqs per kilogram. We're going to study up to 80 KBqs and for six cycles or 12 cycles of therapy. I talked about the earlier disease setting and the combination setting. But we're also going to study other tumor lines, particularly breast cancer, but also potentially osteosarcoma, amongst others. So this is really rounding up the profile of Xofigo. Once again, this program will be almost two to three times the size of the initial program that brought us to the market.

The final compound I'm going to talk about is Adempas, riociquat. This was our agent for pulmonary arterial hypertension. Our pivotal studies were done in pulmonary arterial hypertension. And a type of pulmonary hypertension secondary to blood clots going to the lungs -- CTEPH. Those results were published in the New England Journal of Medicine with an accompanying editorial.

Now we strongly believe -- and I'm glad to say that was shared by the Advisory Committee of the FDA who voted 11-0 in our favor -- that this is a significant advance in pulmonary arterial hypertension.

Now one of the things I guess we've been challenged with is you're just a kind of super PDE-5. That isn't the case.

First of all, we've shown benefit in CTEPH, something that no other therapy has shown. And, thirdly, and beyond that, we believe we work beyond being purely a vasodilator. We think we've got anti-fibrotic, anti-proliferative and anti-inflammatory actions. And this is shown in preclinical models where we've been shown versus PDE-5 inhibitor -- you can see the graph up there -- to show benefit in terms of an animal model of fibrosis where a PDE-5 inhibitor didn't work.

But the proof of the pudding, of course, is in the eating. And so we're going to run a clinical program to maximize on those opportunities. And we're going to study two distinct areas.

The first of this is idiopathic interstitial pneumonia. This is an infiltrate of non-infectious origin into the lung. You get pulmonary fibrosis as a consequence of this and pulmonary hypertension. And we're going to study this. There are no approved therapies in this area.

And the second area is diffuse systemic sclerosis, a debilitating condition characterized by fibrosis. Once again, no approved therapies. And we'll be studying the Adempas in this area. So this will demonstrate our commitment to the value of Adempas. But also showing that we believe it has significant capabilities over and beyond being a vasodilator.

So in summary, I've proven, or hope I've shown, a proven commitment and ability to innovate. And we talked about the five assets we want to take forward in our early clinical program into Phase III.

We want to enhance the profile of the compounds we have on the market by a very extensive Life-cycle Management program. The Life-cycle Management program, for the five assets I've talked about, will take us beyond 40,000 or 50,000 new patients to be recruited into clinical trials with these agents. And we are addressing areas of unmet medical need.

Now look, every company says that. I guess as we're entering autumn and the leaves are turning brown and the days are getting colder, companies are unveiling their shiny new R&D strategies. It seems to be you can't open the newspaper without some head of R&D talking about his new R&D strategy, or her new R&D strategy.

And one of the things they all talk about is we're going to address areas of high unmet medical need. We're going to address our area. You kind of feel someone is going to get up one day and say we're going to buck the trend and we're going to address areas of high unmet need. But I guess that's not going to happen. But the point here is it's one thing saying you're going to try and address those. It's another one to actually do that.

What we have shown by the assets we have got -- and I think by the assets we will take forward -- is our ability to have great science. There's no doubt about that. We can innovate. But also turn that great science into meaningful medical solutions for patients. And I think that'll be the differentiation.

Every company is going to say they're going to address areas of high unmet medical need. Have they got the track record of turning that innovation into meaningful medical solutions? And for me, that's what science for a better life is, having great science but turning that into medical solutions for patients so they have great lives.



So with that, I'll stop. I guess you'll have some questions. But those will have to wait until the round tables that we're going to do a little later.



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